

Medtronic

Restoring life's rhythm

Pulsed field ablation

The Medtronic PulseSelect™ pulsed field ablation system can be used to treat drug refractory, recurrent, symptomatic paroxysmal (PAF), and persistent (PsAF) patients. Talk to your doctor about your treatment options.



About your AFib

Atrial fibrillation (AFib) is an irregular heart rhythm (arrhythmia) that affects the upper chambers (atria) of the heart. This arrhythmia prevents blood from being pumped efficiently to the rest of your body.

AFib may impact your ability to perform daily activities, cause you to feel tired, and impact your overall quality of life. If left untreated, it may increase the risk of heart failure, stroke, and death. In fact, AFib increases the likelihood of having a stroke by five times. Even without symptoms, AFib can be a serious medical condition.

It is important to work with your doctor to make sure you get the right treatment for your heart condition.

Your symptoms

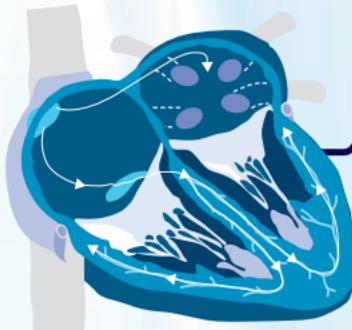
AFib symptoms vary depending on how advanced your AFib is, its cause, and your overall health. You may notice ...



Irregular, rapid,
fluttering, or
pounding heartbeat

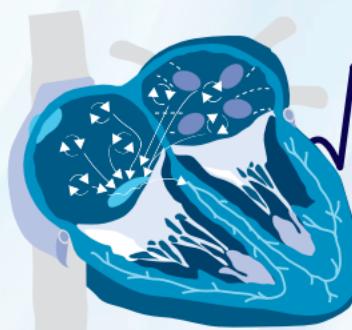


Fatigue, shortness
of breath, or
weakness



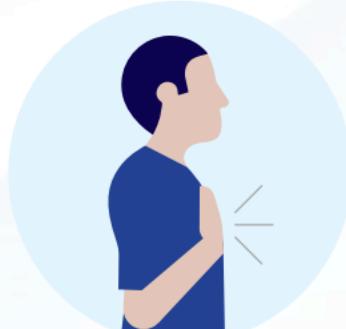
Normal heartbeat

Flow of electrical signals in a normal heartbeat.



Atrial fibrillation

Atrial fibrillation with abnormal signals originating in the atria.



Chest discomfort
or pain



Dizziness

Why did I get AFib?

The causes of atrial fibrillation are often unclear. AFib may be the result of:

- Heart abnormality from birth
- Damage to the heart from a heart attack
- Heart valve problems

People with otherwise normal hearts may also develop AFib.

Risk factors

- | | |
|--------------------|-----------------------------|
| • High cholesterol | • High blood pressure |
| • Heart disease | • Smoking |
| • Excess weight | • Caffeine |
| • Alcohol abuse | • Lack of physical activity |
| • Some medications | • Family history |
| • Sleep apnea | • Heart disorder |
| • Advancing age | |

Why treat now?

There are several reasons your doctor may be recommending ablation:

- Patients with AFib have better results when treated with ablation earlier.
- AFib is a progressive disease and, if left untreated, will continue to get worse.
- Some patients who receive ablation therapy have a lower rate of AFib disease progression compared to treatment with medications alone.

Treating your AFib

The goals of your AFib treatment are to:

- Reduce AFib symptoms and improve your quality of life.
- Prevent blood clots with anticoagulation medication to decrease the risk of stroke.
- Control the heart rate to allow the ventricles (lower heart chambers) enough time to fill with blood.
- Reset the heart rhythm to allow the atria (upper chambers of the heart) and ventricles to work together more efficiently. This is also known as restoring sinus rhythm.



Cardiac ablation

Cardiac ablation is a minimally invasive procedure that can be used to control heart rhythm. Until now, the cardiac catheter ablation energy sources that are typically used to treat AFib are thermal energy: radiofrequency (heat) and cryoablation (cold). Pulsed field ablation delivers short bursts of non-thermal energy and is a safe and effective way to treat certain types of AFib. This procedure is performed by an electrophysiologist (EP) who specializes in the treatment of heart arrhythmias.

What is pulsed field ablation (PFA)?

The goal of a PFA procedure is to stop unwanted electrical signals causing the irregular heart rhythm. Since PFA is a non-thermal energy source, PFA allows for specific areas within the heart to be treated where the unwanted electrical signals are coming from while reducing damage to other parts of the body.



PulseSelect
Pulsed Field
Ablation Catheter

Talk to your doctor to see if PFA is right for you.

The Medtronic PulseSelect pulsed field ablation (PFA) system was engineered with differentiated safety features from 15 years of research and backed by the results of one of the safest Food and Drug Administration (FDA) reviewed AFib ablation trials to date.

The design of the Medtronic PulseSelect PFA catheter allows for therapy to stop the unwanted electrical signals causing the irregular heart rhythm.

PFA is a safe and effective alternative after medication to control your AFib that may improve your quality of life. Only you and your doctor can determine what the right treatment is for you. Speak with your physician today regarding the risks and benefits of PFA.

0.7%
safety event rate

Medtronic PulseSelect pulsed field ablation catheter had a procedural safety event rate of 0.7%, the lowest rate of any FDA-approved system for pulsed field cardiac ablation available today.



Your pulsed field ablation procedure

Your doctor will discuss the procedure with you in detail, but here is a general overview of what you can expect.

Before

Your doctor will probably tell you not to eat or drink after midnight the night before your procedure. You may be under general anesthesia for the procedure. You may need to stop certain medications. You will also want to tell your doctor immediately about any changes in your health.

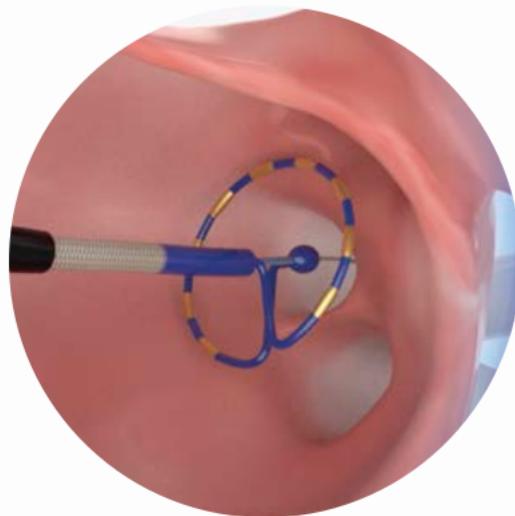
After

You will need to limit your activities for a couple of days. Minor soreness in the chest or bruising at the insertion site (groin) is normal. As your heart heals, it is common to have some AFib symptoms. Your doctor may prescribe medication to help and arrange follow-up visits to monitor your healing and heart rhythm. Let your doctor know if you experience any symptoms that are bothering you.

During the procedure

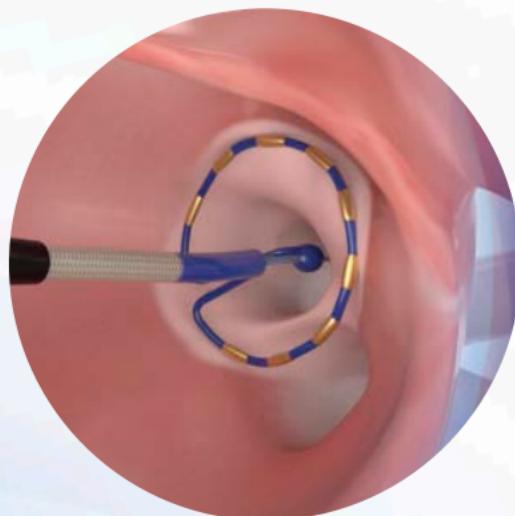
Access

The doctor makes a small incision in the groin area to insert the catheter. To access the left side of your heart, the doctor must cross thin tissue that separates the left and right sides of the heart. The PulseSelect PFA catheter is then advanced to the left atrium.



Ablate

When the PulseSelect PFA catheter is in position, the doctor introduces pulsed field energy into the catheter. The pulsed field energy disrupts and stops the irregular electrical signals that cause AFib.



You may be wondering ...

Is pulsed field ablation safe?

Pulsed field ablation with the Medtronic PulseSelect PFA catheter is generally considered to be a safe and effective treatment for AFib when medication isn't sufficient. It is a minimally invasive procedure, meaning there is no need to open the chest or make large incisions. The most common problem is local irritation or bleeding at the site of the incision. The risk of more serious complications is small, but you should talk to your doctor about whether the procedure is right for you.

How effective is ablation?

Cardiac ablation has been shown to effectively treat AFib, improving symptoms and quality of life for many patients. Generally, the earlier your AFib is treated with ablation, the more successful it may be. Of course, every patient's experience is different. Sometimes after the procedure you will continue to have AFib episodes and may need a repeat procedure. It's also possible that you may need to continue with some type of medication. Be sure to discuss this and any other concerns you might have with your doctor.

My symptoms come and go. Do I need to have a procedure?

AFib can be a serious medical condition that should be treated no matter what level of symptoms you experience. Without effective treatment, AFib may lead to a stroke, heart failure, or other health complications. If your AFib does not improve after the use of medication, speak to your doctor about whether or not an ablation is the next step for you.

What are the risks and complications?

Cardiac ablation is generally a safe procedure. Complications are rare, but can be serious. Risks may include bleeding and bruising where the catheter was inserted, discomfort, chest pain, new or worsening heart conditions, new or worsening breathing conditions, infection, temporary or permanent stroke, severe complications leading to hospitalization, or potentially death. Always talk with your doctor about diagnosis and treatment information.

Where can I get more information?

For more information about atrial fibrillation or the PulseSelect PFA system, visit medtronic.com/AFib, or call the toll-free Medtronic Patient Services line: 1-800-551-5544.

Procedure information for catheter ablation:

Complications, while infrequent, can occur during catheter ablation. Some of the risks include bleeding and bruising where the catheter was inserted, discomfort, chest pain, new or worsening heart conditions, new or worsening breathing conditions, infection, temporary or permanent stroke, severe complications leading to hospitalization, or potentially death. Your physician can further explain these complications as a part of a comprehensive risk/benefit evaluation, as you consider catheter ablation for your condition.

This treatment is prescribed by your physician. This treatment is not for everyone. Please talk to your doctor to see if it is right for you. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of this treatment, results may vary. Information on this site should not be used as a substitute for talking with your doctor. Always talk with your doctor about diagnosis and treatment information. For further information, please call the Medtronic toll-free number at 1-800-551-5544 (8:00 a.m. to 5:00 p.m., Monday-Friday, CT) or see the Medtronic website at medtronic.com.

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